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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/799,910	02/13/97	FALB D	7853-067

HM22/0128

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EXAMINER	
NGUYEN, D	

ART UNIT	PAPER NUMBER
1633	11

DATE MAILED: 01/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 08/799,910	Applicant(s) Falb et al.
	Examiner Dave Nguyen	Group Art Unit 1633

☒ Responsive to communication(s) filed on *Nov 10, 1998* .

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *70, 71, 74, and 77-102* is/are pending in the application.

Of the above, claim(s) *90-96* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *70, 71, 74, 77-89, and 97-102* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *13*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The specification has been amended, claims 72, 73, 75, and 76 have been canceled, claims 70, 71, 74, 77, and 80-87 have been amended, and claims 97-102 have been added by the response filed November 10, 1998.

Election/Restriction

Applicant's election with traverse of Group I in the response dated November 10, 1998 is acknowledged. The traverse is on the grounds (the response, page 6 bridging page 7) that a search directed to the purified preparations of proteins will inevitably reveal any DNA molecules encoding such proteins, and that a search of both groups at once imposes minimal burden upon the examiner, the comments are not persuasive because inventions I and II are directed to different statutory classes of invention. In addition, the polynucleotides of Group I are a fundamentally different type of molecule than the polypeptides of Group II, and the polynucleotides for Group I can be used other than to produce the protein of Group II; for instance, it can be used as a probe in nucleic acid hybridization. The protein of Group II can be used for procedures other than the production of antibodies, such as in treatment of patients with the isolated protein. Thus, these groups are directed to physically and functionally distinct elements, and are therefore patentably distinct; and are not required one for the other.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 90-96 drawn to an invention non-elected with traverse in

the response filed November 10, 1998. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) MPEP 821.01.

Elected claims 70, 71, 74, 77-89, and 97-102 are pending to which the following grounds of rejection remain and/or are applicable.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application 60/011,787); the disclosure of the invention in the provisional application and in this instant application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *In re Ahlbrecht,* 168 USPQ 293 (CCPA 1971). The provisional application 60/011,78, filed February 16, 1996, does not disclose SEQ ID NOS 9 and 10 which are claimed in this instant application. The provisional application 60/011,787 does not contain a written description and an enabling disclosure of claims drawn to SEQ ID NOS 9 and 10, and therefore, the priority for claims drawn to SEQ ID NOS 9 and 10 can only be granted to the filing date of the instant application, February 13, 1997.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> a person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness

rejections set forth in this Office action:

> a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 70, 74, 77, 80-85, 87, 97, 98, 100-102 are rejected under 35 U.S.C. 102(a) as being anticipated by Kondratyev *et al.* (Cancer Res, 56, 1489-1502, April 1, 1996, IDS).

Claims 70, 74, 77, 80-85, 87, 97, 98, 100-102 are drawn to DNA sequences encoding the fchd605 coding region (SEQ ID Nos: 9 and 10). Expression vectors, host cells, and DNA sequences further comprising a label are also recited in the claims. Kondratyev *et al.* teach the cloning and sequencing of a radiation inducible glycosylated human early-response gene (IEX-1) which has 100% match to the polypeptide coding sequence of SEQ ID NO: 9, *e.g.*, see Fig. 2 of Kondratyev *et al.*, and sequence comparison generated by a database search using Smith-Waterman algorithm, nucleotide residues 1-479 of SEQ ID NO: 9. Kondratyev *et al.* also teach expression vectors, heterologous regulatory sequences operably linked to the IEX-1 mRNA, eukaryotic host cells, cDNA sequences containing a label (see Materials and Methods, Figs. 1-4).

Absent evidence to the contrary, and in the alternative, the polynucleotide sequence of Kondratyev *et al.* has all of the properties cited in the claims.

Claims 70, 71, 74, 77, 80-87, 97-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kondratyev *et al.* (Cancer Res, 56, 1489-1502, April 1, 1996, IDS).

The claims are drawn to SEQ ID NO: 9, expression vectors, and host cells containing SEQ ID NO: 9. Kondratyev *et al.* teach the cloning and sequencing of a radiation inducible glycosylated human early-response gene (IEX-1) which has 100% match to the polypeptide coding sequence of SEQ ID NO: 9, *e.g.*, see Fig. 2 of Kondratyev *et al.*, and sequence comparison generated by a database search using Smith-Waterman algorithm, nucleotide residues 1-479 of SEQ ID NO: 9. While the sequence comparison shows that there are 7 mismatches between the DNA sequence of Kondratyev *et al.* and the SEQ ID NO: 9 in the intronic region (non-coding DNA sequence), it would have been obvious to one skilled in the art that the DNA sequence of Kondratyev *et al.* is an obvious variant of SEQ ID NO: 9, particularly since both sequences encode the same polypeptide sequence, and since the seven mismatches are located in the intronic region which does not affects the activity of the encoded polypeptide product. It would also have been obvious for one of ordinary skilled in the art to have employed known prokaryotic and/or eukaryotic cell lines to express the polypeptide product encoded by the IEX-1

gene for use in a glycosylation assay, as taught by Kondratyev *et al.*

Absent evidence to the contrary, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

No claims are allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on November 10, 1998 prompted the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL . See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE - MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Brian*

Stanton, may be reached at **(703) 308-2801**

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 304-0196**.

Dave Nguyen

Bruce Campell

BRUCE R. CAMPELL
PRIMARY EXAMINER
GROUP 1800